

1 IN THE UNITED STATES DISTRICT COURT
 2 IN AND FOR THE DISTRICT OF DELAWARE
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 4 SHIRE ORPHAN THERAPIES LLC and) Civil Action
 5 SANOFI-AVENTIS DEUTSCHLAND)
 GMBH,
)
 6 Plaintiffs,
)
 7 v.
)
 8 FRESENIUS KABI USA, LLC,
)
 9 Defendant.) No. 15-1102-GMS
 10 - - -

11 Wilmington, Delaware
 12 Tuesday, January 23, 2018
 13 10:00 a.m.
 Telephone Conference
 14 - - -
 15 BEFORE: HONORABLE GREGORY M. SLEET, Senior Judge, U.S.D.C.,
 District of Delaware
 16 APPEARANCES:
 17 JACK B. BLUMENFELD, ESQ., and
 DAREN J. FAHNESTOCK, ESQ.
 Morris, Nichols, Arsh & Tunnell LLP
 -and-
 18 EDGAR J. HAUG, ESQ.,
 SANDRA KUZMICH, PH.D., ESQ.,
 LAURA A. CHUBB, ESQ., and
 ELIZABETH MURPHY, ESQ.
 Haug Partners LLP
 (New York, NY)
 19 Counsel for Plaintiffs
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 21
 22
 23
 24
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10:03:25 1 schedule.
 10:03:27 2 This semester, I teach a course in patent
 10:03:32 3 litigation at Duke, which I have taught basically every
 10:03:35 4 other semester for a bit of time now.
 10:03:38 5 We will work on -- I teach the course Thursday
 10:03:41 6 evening -- we will work on Thursday morning from 9 to 11,
 10:03:47 7 when I need to leave, get myself to the airport, and resume
 10:03:53 8 the next day at 10:30, is my plan. My plane gets me there
 10:04:02 9 in time to possibly get on the Bench by 10, but certainly by
 10:04:05 10 10:30 barring any travel mishaps.
 10:04:10 11 Let me find out, since you guys gave me some new
 10:04:16 12 news this morning, I thought I would give you some, let's
 10:04:20 13 find out how that will impact your planning and thinking. I
 10:04:24 14 know you are just processing this. I know we set aside five
 10:04:28 15 days. It seemed like a lot to me for a one-patent case.
 10:04:32 16 Let's begin with plaintiff.
 10:04:35 17 MR. BLUMENFELD: Your Honor, I don't think that
 10:04:39 18 should be a problem. It sounds like we will have four days
 10:04:44 19 plus a little more. We were hopeful of finishing the trial,
 10:04:51 20 as Your Honor suggested, in a little less than five full
 10:04:55 21 days anyway. We should be able to work around that and
 10:04:59 22 still finish on Friday.
 10:05:03 23 THE COURT: From defendant's point of view?
 10:05:13 24 MR. JAMES: Your Honor, we agree with what Mr.
 10:05:17 25 Blumenfeld just said, that we think there should be adequate

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1 APPEARANCES CONTINUED:

2 KAREN E. KELLER, ESQ.
 Shaw Keller LLP

3 -and-

4 DARYL L. WIESEN, ESQ.
 WILLIAM G. JAMES, ESQ.,
 JOHN COY STULL, ESQ., and
 5 SAMUEL SHERRY, ESQ.
 Goodwin Procter LLP
 (Washington, DC)

6 Counsel for Defendant
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10:02:30 9 THE COURT: Good morning, counsel. Who is on
 10:02:32 10 the line for the plaintiffs this morning?

10:02:34 11 MR. BLUMENFELD: Good morning, Your Honor. It's
 10:02:36 12 Jack Blumenfeld and Derek Fahnestock from Morris Nichols,
 10:02:40 13 along with Ed Haug, Sandy Kuzmich, Liz Murphy, and Laura
 10:02:46 14 Chubb from Haug Partners in New York.

10:02:48 15 THE COURT: Good morning.
 10:02:50 16 For the defendant.

10:02:53 17 MS. KELLER: Good morning, Your Honor. Karen
 10:02:55 18 Keller from Shaw Keller. With us today is Bill James, Daryl
 10:03:00 19 Wiesen, Koy Stull, and Sam Sherry from Goodwin Procter.

10:03:04 20 THE COURT: So if counsel, for the record, if
 10:03:10 21 you would just let us all know who is speaking, since there
 10:03:13 22 are multiple lawyers on the line for each party, that would
 10:03:16 23 be helpful.

10:03:18 24 I don't think we have a ton to talk about today.
 10:03:20 25 The first thing I need to mention is the

10:05:20 1 time in that schedule to finish the trial next week.
 10:05:23 2 THE COURT: Great. Okay. Let's go to Exhibit
 10:05:29 3 14. I got your letter.
 10:05:32 4 MR. BLUMENFELD: Your Honor, just to fill you in
 10:05:38 5 on Exhibit 14 and Exhibit 15, I think as a result of
 10:05:45 6 conversations that the parties have had over the last few
 10:05:51 7 days, we have resolved all of the issues in the cover order
 10:05:56 8 and we have resolved most of the issues in Exhibit 14 and
 10:06:01 9 15.
 10:06:01 10 The only three evidentiary issues that I think
 10:06:04 11 are left are the issue we raised about Dr. Raines, the issue
 10:06:11 12 that the defendant raised about our expert, Ms. Ellis, and
 10:06:18 13 an issue that the defendant raised in a letter to Your Honor
 10:06:23 14 last night.
 10:06:27 15 We are also to happy to just take them up at
 10:06:30 16 trial since they are all kind of witness issues, whichever
 10:06:34 17 Your Honor would prefer.
 10:06:36 18 THE COURT: How does the other side feel?
 10:06:41 19 MR. JAMES: Your Honor, I will jump in. I think
 10:06:48 20 Mr. Wiesen will handle the issue about from Dr. Raines and
 10:06:51 21 Ms. Ellis.
 10:06:52 22 If I could talk about the other issue we sent
 10:06:57 23 Your Honor last night by letter, so we were trying to give
 10:07:00 24 you the opportunity to look at the issue before the call.
 10:07:07 25 It relates to the schedule. As you know, yesterday, you

10:07:11 1 entered an order in which we dropped our Section 103
 10:07:18 2 obviousness case. The only two defenses remaining are
 10:07:22 3 obvious type double patenting and laches. In that regard,
 10:07:26 4 the plaintiffs have submitted expert reports from Dr. Bell,
 10:07:32 5 who is an economist, and Dr. Kaplan, who is a clinician,
 10:07:37 6 related to secondary considerations.

10:07:41 7 Dr. Bell talks about obviousness in his expert
 10:07:44 8 report, sort of lies the predicate, legal and economic
 10:07:50 9 framework for why we care about commercial success. He
 10:07:54 10 doesn't say anything about obviousness double type
 10:07:59 11 patenting. He doesn't reference the ODP, the obvious type
 10:08:06 12 double-patenting reference patents we are relying on.

10:08:10 13 THE COURT: This is which witness?
 10:08:13 14 MR. JAMES: Dr. Bell. The economist.
 10:08:21 15 Dr. Kaplan also, he doesn't talk about
 10:08:25 16 obviousness type double patenting or obviousness, for that
 10:08:29 17 matter. He doesn't talk about the reference patent, the
 10:08:33 18 7803 patent we are calling it in this case.

10:08:38 19 Your Honor, we didn't have notice under Rule 26
 10:08:40 20 about these opinions relating to the obviousness type double
 10:08:45 21 patenting argument. We couldn't have our experts respond to
 10:08:50 22 whatever assertions they might make about why these things
 10:08:54 23 are relevant. We couldn't take their depositions because
 10:08:57 24 they weren't in their expert reports.

10:08:59 25 We don't think they should be testifying at

10:10:40 1 We relied on secondary considerations, long-felt
 10:10:43 2 need and commercial success. This is a little bit of a --
 10:10:47 3 it feels like a little bit of a trick here.
 10:10:51 4 Yesterday Fresenius dropped obviousness, then
 10:10:54 5 last night they say, okay, now you can't put in your
 10:10:57 6 secondary considerations. Although secondary considerations
 10:11:03 7 went to both obviousness and obviousness type double
 10:11:07 8 patenting, and they don't change and the discovery doesn't
 10:11:09 9 change, the reports don't change, the depositions don't
 10:11:12 10 change, depending on whether it goes to obviousness or
 10:11:16 11 obviousness type double patenting.

10:11:18 12 On the legal point, it's clear that secondary
 10:11:20 13 considerations, like commercial success and long-felt need,
 10:11:26 14 are relevant and are as relevant to obviousness type double
 10:11:31 15 patenting as to obviousness. Your Honor had this issue in
 10:11:33 16 the Eli Lilly v. Teva case back in 2011 or 2012 where you
 10:11:40 17 excluded evidence of secondary considerations going to
 10:11:45 18 obviousness type double patenting because of a footnote in a
 10:11:50 19 Federal Circuit case, the Geneva, said that was erroneous,
 10:11:58 20 they affirmed your opinion but said your secondary
 10:12:03 21 consideration evidence was erroneous.

10:12:05 22 More recently, in UCB v. Accord in 2016, Judge
 10:12:11 23 Stark said, and I will quote his opinion, 201 F.Supp. 3rd.
 10:12:16 24 491 at 536, "Generally, when considering whether a patent is
 10:12:21 25 invalid for obviousness type double patenting, the Court is

10:09:02 1 trial on the obviousness type double patenting defense. By
 10:09:08 2 the same token, if they do not put in evidence on commercial
 10:09:13 3 success through Dr. Bell, their economist, and Dr. Kaplan,
 10:09:16 4 their clinician, we wouldn't put in our counterpart, Dr.
 10:09:19 5 Hofmann, our economist and Dr. Pines, a clinician.

10:09:23 6 THE COURT: So it's a notice issue.

10:09:27 7 MR. JAMES: It is.

10:09:29 8 THE COURT: Could I hear a response, please.

10:09:32 9 MR. BLUMENFELD: Your Honor, it is really not a
 10:09:34 10 notice issue. They had full notice of everything that Dr.
 10:09:38 11 Bell and Dr. Kaplan were going to talk about. Dr. Bell is
 10:09:42 12 an economist. Dr. Kaplan is a physician, a doctor.

10:09:47 13 When their reports were done, they didn't talk
 10:09:50 14 about obviousness or about obviousness type double
 10:09:54 15 patenting. They talked about the commercial success in Dr.
 10:10:01 16 Bell's case, about the long-felt need for the drug in Dr.

10:10:05 17 Kaplan's case.

10:10:07 18 At that time, obviousness was in the case,
 10:10:12 19 obviousness type double patenting wasn't even in the case at
 10:10:16 20 that time. In its findings and conclusions, which are Tab
 10:10:19 21 13 of the pretrial order, Fresenius incorporates its
 10:10:24 22 obviousness section by reference in obviousness type double
 10:10:30 23 patenting. They say that Claim 14, which is the only claim
 10:10:34 24 at issue anymore, is an obvious variant based on the prior
 10:10:39 25 art.

10:12:24 1 required to consider objective indicators of
 10:12:28 2 nonobviousness of such evidence if presented."

10:12:33 3 We have presented it. It doesn't change because
 10:12:37 4 they dropped obviousness and are only asserting obviousness
 10:12:41 5 type double patenting.

10:12:42 6 It is the same evidence we presented in our
 10:12:45 7 report and the depositions. Nothing about it changes.

10:12:49 8 THE COURT: I will hear a brief response.

10:12:53 9 MR. JAMES: Your Honor, Mr. Blumenfeld is right

10:12:56 10 that the Federal Circuit said that secondary considerations
 10:13:00 11 can be relevant in obviousness type double patenting
 10:13:04 12 contexts. But you have to demonstrate how they are
 10:13:11 13 relevant. So here we are not arguing obviousness over the
 10:13:15 14 prior art per se.

10:13:16 15 There is a patent that is owned by Hoechst that
 10:13:21 16 claims an intermediate to the compound that is claimed in
 10:13:24 17 this litigation, and there is no effort made by the
 10:13:31 18 economist or the clinician, doctor/clinician, to demonstrate
 10:13:36 19 how either one of their factors would be relevant in that
 10:13:40 20 context.

10:13:41 21 So, yes, it can be relevant, but it has to be
 10:13:45 22 demonstrated how it's relevant in the particular
 10:13:47 23 circumstances. None of that is in the expert report.

10:13:52 24 Again, it is not even mentioned. We didn't have the
 10:13:55 25 opportunity to vet that in discovery.

10:13:58 1 We are not saying that it's per se out in an ODP
 10:14:03 2 context, that is not right. We understand secondary
 10:14:07 3 considerations can be relevant. But we weren't on notice as
 10:14:10 4 to how they were going to try to prove that up.

10:14:12 5 THE COURT: Okay.

10:14:13 6 Mr. Blumenfeld.

10:14:14 7 MR. BLUMENFELD: Your Honor, I really don't
 10:14:17 8 understand that point, because the issue here is whether
 10:14:23 9 there are secondary considerations that apply to Claim 14.
 10:14:28 10 Their claim is that Claim 14 is an obvious variant based on
 10:14:36 11 a certain reference and based on other prior art which they
 10:14:40 12 were till yesterday also relying on for obviousness.

10:14:43 13 It doesn't change the analysis to say the
 10:14:47 14 invention of Claim 14 was a commercial success, the
 10:14:51 15 invention of Claim 14 satisfied a long-felt need, to say
 10:14:56 16 that somehow that is different if it is a double patenting
 10:14:59 17 obviousness analysis or a straight obviousness analysis.

10:15:05 18 A couple weeks ago, when Your Honor permitted
 10:15:08 19 double patenting to come into the case, Fresenius told you
 10:15:12 20 that all of the discovery that was needed was done. So now
 10:15:17 21 to hear that somehow something wasn't done is a little
 10:15:22 22 surprising to us.

10:15:24 23 Nothing changes. The only thing I heard was
 10:15:27 24 that they didn't tell us that these same facts that they are
 10:15:31 25 relying on for commercial success and for long-felt need now

10:17:06 1 was a reasonable statement at all. The question in either
 10:17:11 2 case, whether it is obviousness or obviousness type double
 10:17:15 3 patenting, was whether the invention was obvious at the time
 10:17:19 4 of the invention. The questions about secondary
 10:17:25 5 considerations go to exactly the same thing, whether for 103
 10:17:29 6 or for double patenting it was obvious at the time of the
 10:17:34 7 invention. The commercial success and long-felt need are
 10:17:38 8 the same, exactly the same in either case.

10:17:40 9 THE COURT: Counsel for defense, Mr. James, I
 10:17:51 10 can't see how it would be prudent for the trial judge, for
 10:17:55 11 me, at this juncture, to exclude this evidence, given what I
 10:18:03 12 have just heard. Why wouldn't it make more sense to go
 10:18:07 13 ahead and listen to the evidence and give counsel a chance
 10:18:10 14 to renew your discussion either during the trial, perhaps at
 10:18:16 15 two different times, after the witnesses have testified
 10:18:20 16 and/or posttrial? Why risk having to do this again by
 10:18:28 17 having me perhaps prematurely preclude the witnesses? The
 10:18:36 18 record will be more fully developed and I will have a
 10:18:40 19 more clear picture than I frankly do today, given the
 10:18:45 20 limited opportunity I have had to understand the issue and
 10:18:48 21 its relatively late presentation to the Court.

10:18:52 22 Can you tell me why it would be prudent for me
 10:18:55 23 to act now rather than later?

10:18:58 24 MR. JAMES: Your Honor, I understand your
 10:19:00 25 concern. Certainly, we will renew whatever objections we

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10:15:35 1 apply to whether Claim 14 is an obvious variant as opposed
 10:15:40 2 to whether Claim 14 was obvious under a straight 103
 10:15:45 3 analysis. There is nothing different about it.

10:15:48 4 THE COURT: Last word, counsel.

10:15:51 5 MR. JAMES: Your Honor, if I could.

10:15:54 6 It makes all the difference in the world whether
 10:15:56 7 we are talking about obviousness over the prior art which
 10:16:00 8 arose prior to 1989 or over this intermediate claimed in a
 10:16:06 9 patent owned by the plaintiffs that arose in 1997 and how
 10:16:12 10 there is any relevance of the commercial success of the
 10:16:17 11 product ultimately over that compound.

10:16:20 12 The relevance of these two, the long-felt need
 10:16:24 13 and the commercial success, makes all the relevance in the
 10:16:28 14 world which defense we are talking about.

10:16:31 15 On the discovery point, I did tell you that
 10:16:34 16 discovery had been completed. And that was because their
 10:16:38 17 other experts addressed the obviousness type double
 10:16:41 18 patenting argument and we took their depositions on it.

10:16:44 19 That just didn't occur with respect to these two experts.
 10:16:48 20 We had no notice that these opinions were relevant to the
 10:16:51 21 ODP argument.

10:16:54 22 THE COURT: Is that a reasonable statement for
 10:16:59 23 your colleague to make, Mr. Blumenfeld, under the
 10:17:01 24 circumstances?

10:17:03 25 MR. BLUMENFELD: I am sorry, I don't think that

10:19:07 1 have during their testimony and after, in the posttrial
 10:19:10 2 briefs, if that is Your Honor's ruling. But I don't think
 10:19:13 3 you have heard today anything from counsel for the
 10:19:16 4 plaintiffs about how obvious type double patenting was
 10:19:23 5 referenced in these expert reports.

10:19:25 6 THE COURT: I understand your point, Mr. James.
 10:19:29 7 Do you want to respond to that, Mr. Blumenfeld? You didn't
 10:19:31 8 use the magic words, I guess, is sort of what I am hearing.

10:19:35 9 MR. BLUMENFELD: Yes, Your Honor. Those reports
 10:19:38 10 didn't use the terms obviousness type double patenting.
 10:19:43 11 They used the term obviousness. At that time obviousness
 10:19:47 12 was the defense that was pleaded. But they don't analyze
 10:19:53 13 the prior art. They don't discuss either of them. They
 10:19:56 14 don't discuss the prior art. They talk about the invention,
 10:19:59 15 the invention of the '333 patent, the patent in suit, is the
 10:20:03 16 same for both.

10:20:05 17 The analysis of commercial success is the same
 10:20:10 18 for both. These weren't experts that were coming in and
 10:20:12 19 saying let me tell you about the prior art. That has
 10:20:16 20 nothing to do with their testimony.

10:20:17 21 THE COURT: That's what I thought I heard, Mr.
 10:20:20 22 James. I am going to deny your motion, without prejudice to
 10:20:23 23 your renewing your argument as I said earlier.

10:20:27 24 MR. JAMES: I understand.

10:20:29 25 THE COURT: We have No. 1, for this Dr. Raines,

10:20:40 1 that I think the plaintiff complains is a witness I
 10:20:44 2 shouldn't hear regarding prosecution history. Is that
 10:20:48 3 correct, Mr. Blumenfeld?

10:20:49 4 MR. BLUMENFELD: It is, Your Honor. Ms. Ellis
 10:20:51 5 is the other side of that. These are two experts, one a
 10:20:57 6 scientist on their side, a patent person on our side. The
 10:21:02 7 question is whether either of them should be permitted to
 10:21:09 8 testify about the prosecution history. Different reasons by
 10:21:14 9 the different parties as to why they think they shouldn't.

10:21:20 10 Again, I leave it to Your Honor whether you
 10:21:22 11 think it makes more sense to deal with it now or deal with
 10:21:26 12 it at trial when you have context for both of these
 10:21:30 13 witnesses, who they are and what they are saying. If you do
 10:21:34 14 want to hear about it, Mr. Haug is prepared to talk about
 10:21:39 15 both of them. I leave it to you.

10:21:40 16 THE COURT: I am willing to wait if the parties
 10:21:43 17 would prefer. I think you know, and I think Ms. Keller
 10:21:49 18 knows, I wouldn't typically be inclined to hear from
 10:21:53 19 witnesses of this type.

10:21:55 20 MR. BLUMENFELD: Your Honor, these are not
 10:21:58 21 witnesses, I think on either side, who are going to come in
 10:22:01 22 and say, at least on our side, I will talk about our expert,
 10:22:06 23 the patent is not unenforceable because there is a
 10:22:12 24 prosecution laches defense and what Ms. Ellis would do is go
 10:22:17 25 through the file history to explain what happened during

10:23:55 1 We don't intend to have him present opinions
 10:23:58 2 about Patent Office office procedure but rather about the
 10:24:02 3 scientific that have been run by Shire.
 10:24:08 4 Dr. Ellis --
 10:24:10 5 THE COURT: That strikes me as different. I am
 10:24:12 6 agreeing with you.
 10:24:14 7 MR. WIESEN: Dr. Ellis, on the other hand, is a
 10:24:17 8 more classic patent law expert. She has spent her career
 10:24:21 9 working at the Patent Office and then prosecuting patents.
 10:24:23 10 While she does have a Ph.D., they didn't ask her to do any
 10:24:27 11 technical analysis. And she fundamentally runs through the
 10:24:31 12 prosecution history and says this is consistent with this
 10:24:36 13 rule, this is allowed because of this rule, this timing is
 10:24:39 14 allowed to just file a continuation application rather than
 10:24:42 15 provide a substantive response.

10:24:44 16 We think there is really two reasons action that
 10:24:46 17 Dr. Ellis need not testify. The first is what Your Honor
 10:24:50 18 referred to, which is that we can read the prosecution
 10:24:55 19 history here. With a jury trial maybe it would be
 10:24:59 20 different. With a Bench trial, I don't think there is
 10:25:02 21 anything too complicated.
 10:25:03 22 The second issue is whether it is even really
 10:25:06 23 particularly relevant to the prosecution laches issue. If
 10:25:10 24 you look at the case where the Federal Circuit sort of
 10:25:15 25 brought this doctrine back to the forefront about 15 years

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 10:22:21 1 file history. That's why we are offering her.
 10:22:26 2 Again, I leave it to you whether you want to
 10:22:30 3 hear about that on both sides today or in trial where there
 10:22:36 4 is some context for what the issue is.

10:22:38 5 THE COURT: Let's hear the other perspective.
 10:22:43 6 MR. WIESEN: Your Honor, on behalf of Fresenius
 10:22:46 7 on these two issues.
 10:22:48 8 I agree with Mr. Blumenfeld that these are in
 10:22:52 9 some ways two sides of the same coin and they respond to
 10:22:56 10 each other. I think the two parties have taken a different
 10:22:59 11 approach to how to what expert is appropriate to provide
 10:23:03 12 analysis for the Court on the prosecution history related to
 10:23:06 13 the prosecution laches issue.

10:23:09 14 Dr. Raines is a peptide chemist. He is not a
 10:23:12 15 patent lawyer. And the subject matter of his testimony is
 10:23:16 16 to run through the scientific issues related to the
 10:23:21 17 prosecution history, to discuss scientifically what the
 10:23:25 18 Patent Office was asking for the information that Shire or
 10:23:30 19 its predecessor Hopes Kab (phonetic) at the time, and when
 10:23:34 20 they could have provided a scientific response certainly
 10:23:38 21 sets the context for that with the prosecution history. He
 10:23:41 22 can't do that scientific analysis without looking at what
 10:23:44 23 the examiner is asking for. But fundamentally his testimony
 10:23:48 24 is not about the prosecution history but is about the
 10:23:52 25 science related to the prosecution history.

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 10:25:18 1 ago, the Symbol Technologies v. Lemelson case, the way they
 10:25:22 2 ask the question is whether, even though the patentee
 10:25:25 3 complied with the Patent Office procedures, if they delayed
 10:25:28 4 too much without an explanation is laches appropriate.
 10:25:31 5 So having Dr. Ellis show up and explain that
 10:25:34 6 they complied with the Patent Office procedures is
 10:25:36 7 irrelevant. I don't think it's even really disputed. We
 10:25:41 8 are not contesting they didn't comply with the strict orders
 10:25:44 9 of the MPEP and file continuations when they were legally
 10:25:49 10 available.
 10:25:51 11 The argument is despite following those rules,
 10:25:54 12 Symbol Technologies sayings prosecution laches is available
 10:25:57 13 as a defense. That is what our argument is here.
 10:26:00 14 MR. BLUMENFELD: Your Honor, I will defer to Mr.
 10:26:03 15 Haug.
 10:26:03 16 THE COURT: You did say that.
 10:26:04 17 MR. HAUG: No problem. This is Ed Haug.
 10:26:11 18 With respect to first Dr. Ellis, we are not
 10:26:14 19 offering Dr. Ellis as a patent attorney to talk about patent
 10:26:18 20 law. She has been offered based on her expertise and as an
 10:26:24 21 expert Patent Office practice and procedures. I think those
 10:26:29 22 issues are important in this particular case. We are
 10:26:32 23 talking about pre-GATT prosecution. We are also talking
 10:26:36 24 about utilities guidelines that were used by the Patent
 10:26:39 25 Office that are relevant here. She speaks about that, which

10:26:41 1 we think would be helpful to the Court to appreciate the
10:26:46 2 context of the prosecution here.

10:26:48 3 We are not offering Dr. Ellis to talk about the
10:26:51 4 core legal issues of the prosecution and delay or no delay.

10:26:56 5 And also Dr. Ellis was in the Patent Office for
10:27:00 6 about 20 years, including during the relevant time period of
10:27:05 7 the prosecution here, and also in the art group that this
10:27:09 8 application was prosecution in, which is the biotechnology
10:27:13 9 group.

10:27:13 10 We think for all those reasons she would be
10:27:16 11 helpful to the Court to help the Court better understand the
10:27:21 12 prosecution to the extent Your Honor needs that help.

10:27:24 13 That is our view on Dr. Ellis.

10:27:26 14 I think it's r. Raines, it's different, because
10:27:31 15 he is a scientist and has no experience in Patent Office
10:27:35 16 practice. And his report put in in this case, which is very
10:27:38 17 lengthy, doesn't in fact walk through the prosecution. That
10:27:41 18 is the primary reason why we objected.

10:27:43 19 I just heard Mr. Wiesen say maybe he is not
10:27:47 20 going to offer him to do that and he is going to be limited
10:27:51 21 to some scientific opinions which may not be so
10:27:55 22 objectionable if objectionable at all. We won't know that
10:27:58 23 until trial.

10:28:00 24 THE COURT: Let's start there then and gets get
10:28:03 25 Mr. Wiesen to react. I think you are right, Mr. Haug. That

10:29:37 1 issues, what happens with a pre-GATT versus a post-GATT
10:29:44 2 patent and when they expire and how the expiration dates are
10:29:47 3 calculated, some guidelines that they are certainly entitled
10:29:50 4 to cite and argue from, but that I don't think we need a
10:29:53 5 witness to explain.

10:29:55 6 Then running through the prosecution history,
10:29:57 7 which, again, I think, although it's somewhat lengthy, can
10:30:02 8 be done without a witness.

10:30:04 9 THE COURT: Mr. Haug, I tend to not want to
10:30:10 10 spend time doing things from the stand, the witness box, we
10:30:15 11 don't need to spend time doing.

10:30:18 12 With that in mind, I will let the witness take
10:30:22 13 the stand, but I think you should tailor their testimony
10:30:26 14 accordingly.

10:30:27 15 MR. HAUG: Absolutely. Thank you, Your Honor.

10:30:30 16 THE COURT: The same with regard to Dr. Raines,
10:30:32 17 Mr. Wiesen.

10:30:33 18 MR. WIESEN: Absolutely, Your Honor. Thank you.

10:30:36 19 THE COURT: Okay. What do we have left now?

10:30:40 20 MR. BLUMENFELD: Your Honor, I don't think we
10:30:42 21 have anything else. The issues that were raised in the body
10:30:45 22 of the pretrial order, the parties have resolved. I guess
10:30:49 23 that just leaves the question for us whether you want us to
10:30:53 24 submit a new cover order that reflects those agreements or
10:31:01 25 whether the agreements we have are sufficient for your

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10:28:07 1 is what I heard as well.

10:28:10 2 MR. WIESEN: Your Honor, I think that's right
10:28:12 3 with the caveat that, without preferring to the prosecution
10:28:15 4 Dr. Raines can't talk about the scientific issues. In other
10:28:19 5 words, what we will see in the prosecution history is that
10:28:23 6 the examiner was asking for certain kinds of data. We do
10:28:26 7 intend to have Dr. Raines talk about the prosecution history
10:28:30 8 just to the extent he points out that was the type of data
10:28:34 9 that was being requested that talks about the scientific
10:28:36 10 issues about what that data is and what was available.

10:28:40 11 So the prosecution history certainly will come
10:28:42 12 up to set the frame and context.

10:28:45 13 THE COURT: Mr. Haug, with that proviso, would
10:28:49 14 you object?

10:28:50 15 MR. HAUG: I may not with that proviso, if I
10:28:56 16 fully understand it, which I am not sure I will until I hear
10:28:59 17 it.

10:29:00 18 THE COURT: We can do some realtime work as
10:29:03 19 well. I think maybe this witness in your view may be less
10:29:07 20 problematic than you originally thought, perhaps.

10:29:15 21 MR. HAUG: Perhaps. I can't predict.

10:29:18 22 THE COURT: Okay. Go ahead, Mr. Wiesen.

10:29:25 23 MR. WIESEN: That was all I had on Dr. Raines.

10:29:29 24 Dr. Ellis, I think what we heard from Mr. Haug
10:29:33 25 is really that she is going to run through some of the legal

10:31:04 1 purposes.

10:31:04 2 THE COURT: I think they are sufficient, unless
10:31:06 3 counsel feel more comfortable spending the time to submit an
10:31:12 4 additional order. I am comfortable, if the parties are.

10:31:16 5 MR. BLUMENFELD: Certainly the plaintiffs are.
10:31:18 6 We think we know what the agreements are.

10:31:20 7 THE COURT: Mr. Wiesen.

10:31:22 8 MR. JAMES: Your Honor, I would we would be
10:31:26 9 comfortable with that as well. We know what the two or
10:31:29 10 three issues were. We know what the agreement was.

10:31:32 11 THE COURT: Then that's all I need to hear.

10:31:36 12 Anything else then, counsel?

10:31:40 13 MR. HAUG: Your Honor, a question. Your
10:31:42 14 preference for opening statements and length, if at all?

10:31:46 15 THE COURT: I do invite openings with emphasis
10:31:52 16 on brevity. There is inevitably going to be some degree of
10:31:58 17 repetition. I would like the parties to keep it down to a
10:32:04 18 dull roar if you could. After a point, I will get it. I
10:32:11 19 don't anticipate wanting to entertain closings at this
10:32:16 20 juncture. I usually don't.

10:32:18 21 It's not unheard of that I have asked. If I do,
10:32:21 22 I expect good lawyers to get on their feet and even when not
10:32:27 23 completely prepared to respond to Court's questions. But at
10:32:31 24 this juncture, I am not asking you to prepare a formal
10:32:35 25 closings.

10:32:38 1 MR. JAMES: Thank you, Your Honor.
10:32:40 2 MR. WIESEN: Your Honor, as a followup to Mr.
10:32:42 3 Haug's comment.
10:32:44 4 To flag it, I think we put in the pretrial order
10:32:47 5 that the parties have agreed, since it's an invalidity and
10:32:50 6 unenforceability case, that defendants are going to go
10:32:53 7 first. So you are not surprised by that on Monday, I wanted
10:33:00 8 to flag that. Although there is, partially due to some
10:33:04 9 witness availability as well, the expectation is that we
10:33:07 10 will go first on substantive issues, the defendants will
10:33:11 11 rebut, and then the plaintiffs will reply with witnesses on
10:33:14 12 secondary considerations that we have discussed.
10:33:18 13 THE COURT: That is fine. It's almost 20 years,
10:33:21 14 Mr. Wiesen. Tough to find something new under the sun.
10:33:26 15 MR. WIESEN: Understood, Your Honor.
10:33:28 16 THE COURT: Anything else, counsel?
10:33:29 17 MR. JAMES: Your Honor, we do have one witness,
10:33:37 18 Dr. Pines, a clinician, who will be testifying now. As a
10:33:44 19 busy physician, he has some scheduling issues. He can't
10:33:49 20 testify on Wednesday. He can testify on Tuesday or
10:33:54 21 Thursday. I don't know about Friday. I don't think he is
10:33:58 22 available then, either.
10:33:59 23 We will work with the other side to try to make
10:34:02 24 sure that doesn't impact the schedule otherwise.
10:34:04 25 THE COURT: If the parties are comfortable with

10:34:06 1 taking a witness out of turn, if that is the case, if that
10:34:10 2 is what you are suggesting needs to be done, Mr. James, I am
10:34:13 3 fine. If there is an objection, obviously, I have to take
10:34:17 4 it up. I am comfortable with you working that out on your
10:34:20 5 own.
10:34:21 6 MR. HAUG: Your Honor, we have already agreed to
10:34:24 7 allow the witness to go out of turn for his convenience.
10:34:28 8 That is not an issue.
10:34:31 9 THE COURT: Okay.
10:34:31 10 Mr. James, does that satisfy you?
10:34:34 11 MR. JAMES: Your Honor.
10:34:35 12 THE COURT: Okay. Unless there is anything
10:34:39 13 else, have a good week, counsel. Take care.
14 (Conference concluded at 10:35 a.m.)
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